

**Remarks/Arguments**

Reconsideration of the above-identified application in view of the following remarks is respectfully requested. Claims 1-14 are pending in the present application.

**Rejection of Claims 1-14 under 35 U.S.C. §103**

Claims 1-14 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,881,534 to Uhl et al. (hereafter "Uhl") in view of U.S. Patent Appln. No. 2003/0100905 to Mears (hereafter "Mears") and further in view of U.S. Patent No. 5,443,474 to Sfakianos, et al. (hereafter "Sfakianos"). That rejection is respectfully traversed.

Claim 1 recites that a shield section and a guide section project axially beyond the cutting blade to recess the cutting blade in the distal end portion of the shaft member. The Examiner acknowledges that Uhl does not teach this structure (Office Action page 3). The Examiner asserts, however, that Mears cures the deficiencies of Uhl and that it would have been obvious to combine the teachings of Uhl and Mears. The Applicant disagrees.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). 35 U.S.C. § 103 forbids issuance of a patent when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject

matter pertains." In making a determination of obviousness under 35 U.S.C. §103(a):

...the scope and contents of the prior art are determined; the differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. Graham v. John Deere, 383 U.S. 1, 17-18, 86 S. Ct. 684, 15 L. Ed. 2d 545 (1966).

Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, *there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.* KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1741; 2007 U.S. Lexis 4745; 167 L. Ed. 2d 705; 75 U.S.L.W. 4289 (2007) (emphasis added), *citing* In re Kahn, 441 F.3d 977, 988 (CA Fed. 2006). Also, the U.S. Supreme Court noted KSR Int'l. Co. V. Teleflex, Inc., that the analysis supporting a rejection under 35 U.S.C. 103(a) should be made explicit, and that it was "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements in the manner claimed." KSR at 1741.

The reasoning set forth by the Examiner in the Office Action is not articulated and does not include a rational underpinning. In rejecting claim 1, the Examiner's only reason is that it would have been obvious to one having ordinary skill in the art to modify the distal end cutter of Uhl to include a recessed blade, as taught by Mears, to prevent objects from contacting the blade (Office Action page 3). A person

having ordinary skill in the art, however, would not have been prompted to combine the teachings of Uhl and Mears.

Uhl teaches an osteotome 24 for improving the Ilizarov technique. The Ilizarov technique is a limb-lengthening procedure that requires the circumferential severance of the cortex from the bone to be lengthened while minimizing damage to the periosteum and medullary cavity (Col. 1, lines 11-17). In order to facilitate this procedure, the osteotome 24 comprises a rib 14 having a milled cutting end 16 for cutting the bone cortex 23 around the medullary cavity 25. The height of the rib 14, and thus the cutting end 16, corresponds quite closely with the thickness of the cortex 23 of the bone 21 in order to sufficiently penetrate through the cortex 23 without significant penetration into the medullary cavity 25 (Col. 5, lines 15-29 and Figs. 7-8).

The osteotome 24 further includes a bearing surface 15 having a non-cutting leading edge 17 for separating the periosteum 22 from the cortex 23 during use of the device. This configuration protects the periosteum 22 from significant damage and minimizes entry into the medullary cavity 25 while providing a complete annular break in the bone cortex 23 (Col. 6, lines 11-15 and Fig. 11).

Mears teaches a blade 22 recessed between two joint spacers 20 to prevent objects from contacting and damaging the blade 22 (paragraph 20 and Fig. 2). The joint spacers 20 provide a guide to ensure that the ligamentum teres femoris cutter 10 is positioned such that the ligamentum teres femoris 42 can be severed from the femoral head 32 (paragraph 25 and Fig. 9).

It is clear that the purpose of the osteotome 24 of Uhl would be frustrated if the osteotome 24 incorporated a recessed cutting blade of any kind – including the recessed blade 22 taught by Mears. By using an unrecessed blade in Uhl, the entire width of the cut into the bone 21 is limited to the height of the cutting end 16, thereby maximizing removal of the cortex 23 while minimizing damage to the medullary cavity 25. If, however, the osteotome 24 was adapted such that the cutting end 16 were recessed between the bearing surface 15 and the “guide portion” 14, as suggested by the Examiner, the resulting device would be incapable of achieving both of the above-identified objectives. Thus, to combine the teachings of Uhl and Mears contradicts the objective of Uhl and therefore is non-obvious.

The asserted combination of references is problematic, and thus undesirable, for several reasons. While the bearing surface 15 of Uhl is capable of simply moving the periosteum 22 out of the way – as opposed to cutting it – the “guide portion” 14 cannot function similarly with respect to the medullary cavity 25. Since the medullary cavity 25 is much harder than the periosteum 22, the medullary cavity 25 cannot simply be moved out of the way during cutting of the cortex 23. Thus, in order for the “guide portion” 14 to cooperate with the bearing surface 15 to recess the cutting end 16, the “guide portion” 14 would have to avoid the medullary cavity 25 or cut through it. In either case, the resulting structure contradicts the objective of Uhl.

In order to avoid the medullary cavity 25, the combined height of the cutting end 16 and the “guide portion” 14 must be narrower than the cortex 23. Thus, the thickness of the “guide portion” 14 used to recess the end 16 would outwardly offset the cutting end 16 from the medullary cavity 25. Accordingly, the cutting end 16

would be incapable of complete circumferential severance of the cortex 23 from the medullary cavity 25, as desired by Uhl, because a ring or cortex 23 having the thickness of the offset would always remain attached to the medullary cavity 25.

As noted, in order to achieve complete this desired circumferential severance, the cutting end 16 has to closely correspond to the width of the cortex 23. To accommodate this larger cutting end 16 in a recessed configuration, however, the "guide portion" 14 would necessarily be disposed inwards of the cortex 23 during use and therefore be forced to cut through the medullary cavity 25. Cutting the medullary cavity 25 by the thickness of the "guide portion" 14 is not minimizing entry into the medullary cavity 25, as desired by Uhl. Thus, this construction provides undesirable results.

Furthermore, in the sense that the "guide portion" 14 must cut through the medullary cavity 25, the "guide portion" 14 is clearly not guiding anything, and thus this construction also fails to teach the structure of claim 1. Therefore, it is clear that the "guide portion" 14 cannot possibly act as guiding structure and provide an effective cutting height for the cutting end 16 such that the object of the invention in Uhl is maintained. For these reasons, one of ordinary skill would not have been prompted to incorporate the recessed cutting blade construction of Mears into the osteotome 24 as taught by Uhl. Since the combination of Uhl and Mears does not teach the structure recited in claim 1, it is respectfully submitted that claim 1 patently defines over the combination of Uhl and Mears and is therefore allowable.

Claim 2-6 depend from claim 1 and are allowable for at least the same reasons as claim 1 and for the specific limitations recited therein.

Claim 7 recites that the guide section projects axially beyond the shield section. Uhl does not teach this structure. The Examiner asserts that element 14 in Uhl corresponds with the guide section of the present invention. The Examiner further asserts that element 15 in Uhl corresponds with the shield section of the present invention. Thus, it is clear by Figs. 1-2 that the "guide surface" of Uhl does not project axially beyond the "shield section". Mears does not cure the deficiencies of Uhl as neither of the joint spacers 20 in Mears extends axially beyond the other. As best understood, the Examiner did not rely on Sfakianos in rejecting claim 7 and thus the teachings of Sfakianos are not addressed. Since the combination of Uhl and Mears does not teach the structure recited in claim 7, it is respectfully submitted that claim 7 patentably defines over the combination of Uhl and Mears and is therefore allowable.

Claim 8 recites an arcuate cutting blade extending between first and second tip portions. The first tip portion has a shield surface for shielding the cutting blade to prevent undesired cutting of soft tissues. The second tip portion comprises a blunt tooth and acts as a guide. The Examiner acknowledges that the combination of Uhl and Mears does not teach this structure (Office Action page 3). The Examiner asserts, however, that Sfakianos cures the deficiencies of Uhl and Mears and that it would have been obvious to combine the teachings of Sfakianos with Uhl and Mears. The Applicant disagrees.

As noted, one having ordinary skill would not have been prompted to combine the teachings of Uhl and Mears because adapting the osteotome 24 of Uhl with a recessed blade construction produces undesirable results. Applying the teachings of

Sfakianos to the combination of Uhl and Mears, however, produces similar undesirable results, thereby rendering the combination non-obvious.

The Examiner asserts that Sfakianos evidences the use of an arcuate blade between first and second tip portions to reduce the risk of stray cuts and damage to surrounding tissue (Office Action page 3). In particular, Sfakianos teaches a cutting element 40 comprising a curved blade 42 having a leading edge 42a, trailing edge 42b, top edge 42c, and bottom edge 42d. The leading edge 42a includes a concave, sharpened cutting zone 44. The curved blade geometry is designed to catch and guide the meniscal tissue toward the center of the blade 42, thereby reducing the risk of stray cuts and damage to surrounding tissue (Col. 10, lines 18-38 and Fig. 4a). Thus, the convex nature of the alternative cutting zone 44 illustrated in Fig. 4b is inapplicable for this purpose.

The cutting element 40 further includes a broadened flat skid 46 joined to the top edge 42c. The skid 46 is designed to facilitate the passage of the meniscectomy knife into and out of the meniscal region of the knee joint by shielding the surrounding tissue from the curved blade 42 and the cutting zone 44 (Col. 11, lines 10-20 and Fig. 4a). Thus, it is clear that the cutting zone 44 taught by Sfakianos is recessed between the end of the skid 46 and the end of the bottom edge 42d (Fig. 4a). Accordingly, if this curved blade 42 was incorporated into the osteotome 24 of Uhl, the same undesirable results addressed above would be produced – the resulting device would be incapable of maximizing circumferential removal of the cortex 23 from the medullary cavity 25 while minimizing resection of the medullary cavity 25. For these reasons, one having ordinary skill would not be prompted to

combine the teachings of Sfakianos with Uhl and Mears. Since the combination of Uhl, Mears and Sfakianos does not teach the structure recited in claim 8, it is respectfully submitted that claim 8 patentably defines over the combination of Uhl, Mears and Sfakianos and is therefore allowable.

Claims 9-14 depend from claim 8 and are allowable for at least the same reasons as claim 8 and for the specific limitations recited therein.

In view of the foregoing, it is respectfully submitted that the above-identified application is in condition for allowance, and allowance of the above-identified application is respectfully requested.

Please charge any deficiency or credit any overpayment in the fees for this amendment to our Deposit Account No. 20-0090.

Respectfully submitted,

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